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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,231	08/08/2001	Patricia G. Spear	7853-239	3399

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EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	14

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/924,231	SPEAR ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *18 April 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *please see attached*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit: 1648

With respect to the rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, Applicant has argued (1) that there is no heightened how-to-use standard for pharmaceutical compositions; (2) that although there is a greater burden for therapeutic use of a compound than for the compound itself, there is no distinction between claims drawn to a compound and claims drawn to a pharmaceutical composition comprising the compound; (3) that the Examiner has not provided a reasoned basis for the position that *in vitro* experiments disclosed combined with the knowledge available to the ordinarily skilled artisan do not provide a reasonable expectation for success in achieving a beneficial result in administering a pharmaceutical composition comprising HVEM protein; (4) that, in finding the Celniker Declaration unpersuasive, the Examiner has not cited adequate support for the position that there is insufficient basis for extrapolating the *in vitro* result to a reasonable expectation for success in treating human viral infection and that the rejection of claims based on the Examiner's opinion without additional evidence is impermissible; (5) that since claims 1-5 are not limited by any specific use, any enabled use is sufficient to support the claims; and (6) that the specification teaches the use of pharmaceutical compositions for immunizing animals to produce anti-HVEM antibodies.

Applicant's arguments filed April 18, 2003, in Paper No. 13 have been fully considered but they are not persuasive. With respect to point (1), claims drawn to a compound require only one enabled use in order to satisfy the "how to use" requirement of the statute; however, claims drawn to a **pharmaceutical** composition comprising that compound require at least one enabled **pharmaceutical** use in order to satisfy the "how

to use" requirement for the composition. This requirement is not seen to be heightened; it is, however, distinct. With respect to points (2), (5) and (6), claims drawn to "A pharmaceutical composition comprising ... [a compound]" are interpreted to be limited to a pharmaceutical composition and pharmaceutical use of that composition; otherwise the recitation of "pharmaceutical" would be meaningless. See MPEP 2164.01(c) ("When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991)."). With respect to points (3) and (4), the conclusions presented in the Celniker Declaration were based on *in vitro* results only, both those disclosed in the instant specification and those cited in the art, and the prediction presented in the Celniker Declaration was based on a prophetic example, i.e., one that describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. No evidence or persuasive argument has been presented that the state of the art or the nature of the invention supports predictability of successful pharmaceutical use of the claimed compositions. With respect to point (6), administering HVEM to an animal in order to raise antibodies for use in assays is not a pharmaceutical use, since the administration of HVEM is not intended to prevent, diagnose, alleviate, treat, or cure a disease in the animal to which the substance was administered; the animal would merely be used as means of making antibodies that will ultimately be used for another purpose. Thus, to enable a pharmaceutical use for a substance, the specification must teach how to use the

substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered.

The rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, is maintained.

The rejection of claims 1-5 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,303,336 is maintained for reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
May 14, 2003